

Iowa's Vaccines for Children Program Operations Guide



**Iowa Department of Public Health
Immunization Program**

Revised January 2015

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Overview

Welcome to the Iowa Vaccines for Children Program

The Vaccines for Children (VFC) program is a federally funded program providing vaccines at no cost to eligible children from birth through 18 years of age. Eligible children include those who are: enrolled in Medicaid, uninsured, underinsured, American Indian or Alaskan Native. The VFC Program was created by the Omnibus Budget Reconciliation Act of 1993 and was implemented in October 1994 as part of the President's Childhood Immunization Initiative. Funding for the VFC Program is approved by the Office of Management and Budget and allocated through the Centers for Medicare & Medicaid Services (CMS) to the Centers for Disease Control and Prevention (CDC). Children eligible for VFC vaccines are entitled to receive pediatric vaccines recommended by the Advisory Committee on Immunization Practices (ACIP).

The VFC Program is a unique component of the federal Medicaid Program. The VFC Program represents an unprecedented approach to improving vaccine availability nationwide by making federally purchased vaccine available to both public and private immunization providers. With the program in its second decade, it has been recognized for its success in raising immunization coverage rates among high-risk children and reducing disparities in access to health care.

VFC Program Highlights

The VFC Program:

- Provides public-purchased vaccine for eligible children at no charge to VFC-enrolled public and private providers.
- Covers vaccines recommended by the ACIP.
- Saves parents and enrolled providers out-of-pocket expenses for vaccine.
- Eliminates or reduces vaccine cost as a barrier to vaccinate eligible children.
- Reduces the practice of referring children for vaccination.

VFC Operations Guide/Resources

The VFC Operations Guide and other noted resources are intended for the management and operation of the VFC Program. The requirements and procedures are applicable to all providers receiving VFC-funded vaccines.

As changes to this guide occur, an individual module or section will be revised and the date of the latest revision will appear at the top of each page in the module. New information will be posted on the Immunization Program website, and VFC Program providers will be notified.

Enrollment

Enrollment Process

Facility Types

Provider Identification Number

All providers who administer and store VFC vaccine are required to enroll in the VFC Program. Once the enrollment forms are submitted and approved, VFC staff will contact the clinic to set up an initial site visit. This is necessary to comply with federal VFC requirements of an initial site visit. The initial site visit ensures the provider and office staff receive education regarding VFC Program requirements and have appropriate resources to implement the VFC Program.

Some medical providers may have a main clinic and satellite clinics where they provide immunization services. Any satellite clinic storing VFC vaccine must also enroll in the VFC Program.

Enrollment Process

Health care providers must complete the following forms to enroll in the Iowa VFC Program. The Medical Director, or equivalent, shall complete and sign the enrollment forms for the facility.

1. Provider Enrollment Form ([Appendix 1](#))
2. Provider Profile ([Appendix 2](#))
3. IRIS Enrollment Form ([Appendix 3](#))
4. Varicella Vaccine Management Survey ([Appendix 4](#)) (Refer to Vaccine Ordering)
5. Vaccine Storage and Handling Plan ([Appendix 5](#))

New providers can begin ordering and receiving VFC vaccine shipments once an initial VFC enrollment site visit is completed and the provider has documented the vaccine storage units can maintain appropriate temperatures to store vaccine.

Provider Enrollment Requirements ([Appendix 1](#))

Each provider must agree to the following requirements to participate in the Iowa VFC Program:

1. Screen patients, document VFC eligibility status at each immunization encounter and administer VFC-purchased vaccine only to children who are 18 years of age or younger who meet one or more of the following categories:
 - (a) Medicaid enrolled: Children who have health insurance covered by the Iowa Medicaid program.
 - (b) Uninsured: Children who have no health insurance coverage.
 - (c) American Indian or Alaskan Native: As defined by the Indian Health Care Improvement Act.
 - (d) Underinsured: Children covered by health insurance that does not pay for vaccines; and children whose insurance covers only selected vaccines. Those children would be eligible to receive vaccines not covered by insurance. Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC) or Local Public Health Agency (LPHA).
2. Comply with the appropriate immunization schedule, dosage, and contraindications established by the Advisory Committee on Immunization Practices (ACIP), and are included in the VFC Program unless:

- (a) In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child, or
 - (b) The particular requirement contradicts Iowa law, including laws relating to religious or medical exemptions.
- 3. Maintain all records related to the VFC Program for a minimum of three years and upon request make these records available to public health officials or the Department of Health and Human Services (DHHS). VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records verifying receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.
- 4. Immunize eligible children with VFC-supplied vaccine at no charge to the patient for the vaccine.
- 5. Do not charge a vaccine administration fee to non-Medicaid VFC-eligible children exceeding the administration fee cap of \$19.68 per vaccine dose. For Medicaid VFC-eligible children, accept the reimbursement for immunization administration set by the Iowa Medicaid agency or the contracted Medicaid health plans.
- 6. Do not deny administration of a federally procured vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.
- 7. Distribute the current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Compensation Act (NCVIA) which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
- 8. Comply with Iowa's requirements for vaccine management including:
 - (a) Order vaccine and maintain appropriate vaccine inventories.
 - (b) Do not store vaccine in dormitory-style units at any time.
 - (c) Store vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet Iowa Immunization Program storage and handling requirements.
 - (d) Return all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration.
- 9. Agree to operate the VFC Program in a manner intended to avoid fraud and abuse.
- 10. Participate in VFC program compliance site visits including unannounced visits and other educational opportunities associated with VFC program requirements.
- 11. Providers with a signed deputization Memorandum of Understanding between an FQHC or RHC to serve underinsured VFC-eligible children must:
 - (a) Include "underinsured" as a VFC-eligibility category during the screening for VFC eligibility at every visit.
 - (b) Vaccinate "walk-in" VFC-eligible underinsured children.
 - (c) Report required usage data.

Note: "Walk-in" in this context refers to any underinsured child who presents requesting a vaccine, not just established patients. "Walk-in" does not mean a provider must serve underinsured patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations then the policy would apply to underinsured patients as well.

- 12. Pharmacy/pharmacists, urgent care facilities and school-located vaccine clinics must:
 - (a) Vaccinate all "walk-in" VFC-eligible children.
 - (b) Not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee.

Note: "Walk-in" refers to any VFC-eligible child who presents requesting a vaccine, not just established patients. "Walk-in" does not mean a provider must serve VFC patients without an

appointment. If a provider's policy is for all patients to make an appointment to receive immunizations then the policy would apply to VFC patients as well.

13. Replace vaccine purchased with state or federal funds on a dose-for-dose basis deemed non-viable due to provider negligence.
14. Provider or IDPH may terminate this agreement at any time for failure to comply with these requirements or without cause. If the agreement is terminated, the provider must properly return to the VFC Program all unused (viable and non-viable) VFC vaccine.

Practicing Providers

The Provider Enrollment Form is used to document all health care providers practicing at the clinic and their agreement to comply with program requirements. It is necessary to include the NPI (National Provider Identifier) number, medical license number, and e-mail address for each provider listed. If the clinic does not have a physician or nurse practitioner on staff, or does not have an individual NPI number, include the facility's NPI number if applicable. Hospitals enrolled to provide hepatitis B vaccine at birth do not have to list all physicians but may include the medical director, or equivalent, to represent all physicians.

VFC providers shall re-enroll into the VFC Program annually using the Immunization Registry Information System (IRIS). If health care providers practicing at the clinic change during the year, the medical facility must update the physician list in IRIS.

Provider Profile ([Appendix 2](#))

The provider profile, completed either as an individual physician or provider group, is used to establish the number of VFC-eligible children served by the facility for a one-year period. The provider profile allows the Iowa VFC Program to determine how much vaccine a clinic is eligible to receive and ensures VFC-funded vaccine is being administered only to VFC-eligible children.

New providers enrolling in the VFC program shall complete a provider profile. The provider profile is an assessment of the population to be served with VFC vaccine based on the clinic's billing data. Providers determine numbers of VFC-eligible patients based on the clinic's Medicaid claims data and billing data related to self-pay or no health insurance. Non-VFC eligible patients are identified through the clinic's insurance claims billing data. The provider population shall be based on patients seen by the provider during the previous 12 months. The provider shall report the number of children who received vaccinations by age group, counting each child once based on the status at the last immunization visit, regardless of the number of visits made. The provider shall report the number of children by VFC vaccine eligibility categories and non-VFC vaccine eligibility categories.

Annually thereafter, the Iowa VFC Program manages the provider profile data on behalf of the provider. Provider profiles shall be updated when VFC providers re-enroll using data from Iowa's Immunization Registry System (IRIS) and monthly doses administered reports. IRIS captures dose level data from the provider related to VFC vaccine eligibility categories, and VFC vaccine eligibility categories are a required field in IRIS for every vaccine administered. The provider profile can be updated as the facility population changes due to additional medical providers working at the facility or a clinic in the area closing and referring patients to another clinic.

Facility Types

The VFC Program classifies clinics in the following groups:

- Public Health/County Health Department
- Public Health/County Health Department as agent for FQHC/RHC-deputized
- Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC)
- Tribal/Indian Health Services Clinic
- Woman, Infants and Children
- Family Planning
- Juvenile Detention Center
- Correctional Facility
- Drug Treatment Facility
- School-Based Clinic
- Private Hospital
- Private Practice (solo/group/HMO)
- Pharmacy

Federally Qualified Health Center (FQHC)

Federally Qualified Health Centers are public and private non-profit health care organizations meeting certain criteria under the Medicare and Medicaid Programs (Sections 1861(aa)(4) and 1905(l)(2)(B), respectively of the Social Security Act) and receive funds under the Health Center Program (Section 330 of the Public Health Service Act). Health centers are community-based and patient-directed organizations serving populations with limited access to health care.

To inquire about FQHC status, contact HRSA, Bureau of Primary Health Care at (301) 594-4300 or (888) 275-4772. A look-up tool is also available at <http://bphc.hrsa.gov/>.

Rural Health Clinic (RHC)

The Rural Health Clinic Program was established in 1977. Its two-fold purpose is to increase access to health care for rural, underserved communities, and expand the use of nurse practitioners, physician assistants, and certified nurse midwives in rural communities.

Currently, RHCs make up one of the largest outpatient primary care programs for rural underserved communities. RHCs provide comprehensive, family-oriented primary health service to medically underserved and disadvantaged populations experiencing financial, geographical, or cultural barriers to care.

To enquire about RHC status, contact the Iowa Department of Public Health (IDPH), Bureau of Oral and Health Delivery Systems/Office of Rural Health at 515-281-7224.

Provider Identification Number (PIN)

A Provider Identification Number (PIN) is assigned to each enrolled VFC provider site. Using the assigned PIN on all correspondence allows the VFC Program to quickly and accurately respond to providers. It is important to notify the VFC Program and update information in IRIS if there is a change in the clinic enrollment information. This includes changes in the contact person, mailing address, shipping address, practice hours, e-mail address, and medical providers. Updating clinic information ensures accurate provider data and allows for the successful delivery and receipt of vaccine orders in a timely and efficient manner. PINs are assigned to a particular site and do not transfer with a health care provider.

Eligibility

VFC Eligibility Criteria Screening Documentation

VFC Eligibility Criteria

VFC Program providers may only administer VFC vaccine to eligible patients. Children from birth through 18 years of age who meet at least one of the following criteria are eligible to receive VFC vaccine:

- Medicaid enrolled
Children enrolled in any type of Medicaid Program as primary or secondary coverage are eligible for the VFC Program. This includes Medipass, Meridian Health Plan and individuals who have a primary health insurance company and Medicaid as secondary coverage. All are eligible for the VFC Program and should be immunized using VFC vaccine.
- If the primary insurance company does not pay for vaccinations and private stock vaccine was used on a Medicaid-eligible child, IDPH does not have the ability to reimburse providers for the cost of the private purchased vaccine. Iowa Department of Human Services (DHS) – Medicaid Program will not reimburse for acquisition cost of vaccines provided by the VFC Program. DHS will reimburse the provider an administration fee and an appropriate office visit fee.
- Uninsured
- American Indian or Alaskan Native
- Underinsured
Underinsured children include those who have health insurance but the benefit plan does not include immunizations, covers only select vaccines, or caps the vaccine cost at an established limit. Underinsured children are eligible to receive VFC vaccine only if they are served by a Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC) or Local Public Health Agency (LPHA).

As part of the VFC Program, FQHCs and RHCs have the ability to grant FQHC/RHC status to LPHAs to immunize underinsured children on their behalf. Delegation of this authority requires a written agreement between the FQHC/RHC and the LPHA.

Underinsured Eligibility Circumstances

- Children whose health insurance covers the cost of vaccinations are NOT eligible for VFC Program benefits even when a claim for the cost of the vaccine and its administration would be denied if submitted to the insurance carrier for payment because the plan's deductible (high deductible plan) had not been met.
- Some insurance plans may cover all ACIP-recommended childhood vaccines but exclude certain combination vaccines or certain products. A child with this type of coverage would be considered insured and NOT eligible for VFC because all recommended vaccines are covered. Some insurance plans may cover a portion of the cost of the vaccine, even though it may be only a small portion of the cost of the vaccine, this child is considered insured for the purpose of the VFC Program and is NOT eligible for the program.

- Children enrolled in hawk-i are not eligible under the VFC Program because the hawk-i Program is a full coverage insurance plan. Children enrolled in hawk-i must be vaccinated with private vaccine.
- Some insurance plans limit the coverage to a specific number of provider visits annually. If a child's insurance will not cover the cost of vaccine after the child has exceeded the number of provider visits, the child can be considered underinsured for the purposes of the VFC Program because the insurance would not cover the vaccine. The child would be VFC eligible only at an FQHC/RHC/LPHA.
- Persons under 19 years of age who do not know their insurance status and who present at family planning clinics for contraceptive services or STD treatment can be considered uninsured for the purposes of the VFC Program. A person under 19 years of age who may have insurance but because of the confidential circumstances for seeking services in a family planning clinic does not have access to insurance coverage is considered uninsured for the purposes of the VFC Program.
- If a person under 19 years of age loses access to health insurance because of incarceration, the minor is considered uninsured and VFC eligible.

In general, the location where vaccine services are delivered is not a factor in determining VFC eligibility (e.g., LPHA). Children receiving vaccines at a local public health agency cannot automatically be considered VFC eligible. The children must be screened for eligibility, and VFC vaccine can be administered only to VFC-eligible children.

VFC-eligible children, regardless of their state of residence, may be seen at Iowa VFC enrolled provider sites and receive vaccine provided by the Iowa VFC Program. Providers vaccinating Medicaid-enrolled children from another state must enroll as a Medicaid provider in that state to bill for a vaccine administration fee and/or office visit fee.

Refugees, immigrants, foreign-exchange students, and undocumented immigrants should be screened for VFC eligibility just like U.S. citizens. If their native country insurance covers vaccines, they should be vaccinated with private stock. If they do not have insurance or are Medicaid enrolled they should be vaccinated with VFC vaccine.

Screening Documentation

In order for children to receive immunizations through the VFC program, eligibility screening must take place at each immunization visit. Providers must properly and accurately document eligibility status, including eligibility category, at each immunization visit. To be considered accurate, patient records should include the following:

- If Medicaid enrolled, have documentation of Medicaid status (e.g., copy of Medicaid card)
- If Uninsured, have no documentation of insurance or Medicaid enrollment
- If AI/AN, proof of eligibility is not required
- If Underinsured, have documentation of insurance (e.g., copy of card or name/policy #)

To be considered properly documented, the date of the last screening must correspond to the date of the last immunization visit and be different from the date of the previous screening result. VFC providers must use the Patient Eligibility Screening Record ([Appendix 6](#)) or incorporate the screening questions into an existing form. Regardless of how the screening is conducted, the provider must maintain proof of screening in the patient's medical record.

Providers using an electronic health record (EHR) or the Immunization Registry Information System (IRIS) to manage vaccine inventory must have the patient review the Patient Eligibility Screening Record to determine eligibility status. Providers then select the child's current eligibility status to add the new immunizations to the patient record in the EHR or IRIS.

A parent, guardian, or individual of record must indicate the child's eligibility status by selecting one of the categories below:

- Medicaid enrolled
- Uninsured
- American Indian/Alaskan Native
- Underinsured (served by a FQHC, RHC or LPHA)
- Is not eligible for the VFC Program because they do not meet the above criteria

For each child enrolled, a Patient Eligibility Screening Record or equivalent information must be completed and kept on file for at least three (3) years regardless of VFC eligibility.

Vaccine Ordering

***Vaccine Availability
Vaccine Ordering
Ordering Varicella Containing Vaccine
Receiving Vaccine Shipments***

VFC resolutions passed by the Advisory Committee on Immunization Practices (ACIP) form the basis for VFC program policies on vaccine availability and usage. Resolutions may not necessarily match the general usage recommendations of the ACIP, but rather represent the rules providers must follow for administering each specific vaccine under the VFC program. National Center for Immunization and Respiratory Diseases (NCIRD), CDC, and Centers for Medicare and Medicaid Services (CMS) communicate VFC resolutions to state Immunization and Medicaid programs for dissemination to local providers. VFC vaccine must be administered according to the guidelines outlined by the ACIP in the VFC resolutions. VFC vaccine may also be administered in accordance with state school attendance laws.

Vaccine Availability

Iowa VFC Program Vaccine Brand and Presentation Policy

The Iowa VFC Program shall:

- Offer all vaccines listed on the CDC/VFC vaccine contract, unless noted in the Exceptions (see below).
- Allow provider choice between manufacturer and brand.
- Offer vial and syringe presentation when available.

Vaccine Brand and Presentation Exceptions

- Make PPSV 23 available only on a case-by-case basis. Cases shall be identified as high-risk children as defined by the VFC provider and in consultation with the Iowa VFC Program nurse consultant.
- Make Menhibrix available only on a case-by-case basis. Cases shall be identified as high-risk children as defined by the VFC provider and in consultation with the Iowa VFC Program nurse consultant.
- Limit or restrict vaccine products due to constraints and limitations imposed by CDC or the vaccine manufacturer.

The VFC Program shall substitute ordered vaccine with an equivalent vaccine if a provider places an order and the vaccine is unavailable. If a vaccine is unavailable, the IRIS order form shall be updated to show only available products. VFC covered vaccines are listed in [Appendix 7](#).

Vaccine Ordering

Providers are responsible for ordering and maintaining an adequate vaccine supply at their facility. Providers shall submit VFC vaccine orders in IRIS for processing based upon the clinic's established Economic Order Quantity (EOQ). The goal of EOQ is to balance shipping costs with inventory and vaccine wastage costs. Each VFC provider is assigned a vaccine order frequency (monthly, bi-monthly, quarterly) based on the number of doses distributed annually. VFC providers shall place vaccine orders for adequate doses of vaccine to immunize children for the period of time determined by the clinic's EOQ.

Vaccine Ordering Process

The order processing and delivery schedule is subject to change during holidays and extreme weather conditions. Clinics shall allow up to 30 days to receive vaccine orders.

Providers shall:

- Order vaccine quantities consistent with the clinic's established provider profile (doses administered reports) and the number of VFC eligible children served.
- Look at all products needing to be ordered including:
 - Vaccines which may expire before the next ordering frequency
 - Current vaccine inventory (consider historical doses administered data to ensure the clinic does not run out of vaccine before the next order frequency), single antigens and combination vaccines in inventory
 - Seasonality (school physicals, kindergarten round-up)
 - Planned specialty clinics (school based clinics)
- Enter current vaccine inventory (doses on hand) for each vaccine if provider is a non-inventory IRIS user. Doses on hand data shall automatically display on vaccine order form for IRIS inventory users.
- Determine the proper quantity for an order based upon the recommended order quantity displayed on the Create Order screen in IRIS. The recommended order quantity is calculated based on VFC doses administered during the same EOQ period the previous year, doses on hand and package size. The recommended order includes additional doses of vaccine to account for packaging quantity, unexpected need or potential delays.
- Enter the vaccines needed and submit VFC vaccine orders in IRIS.
- Select the day(s) and delivery hours on the Create Order screen in IRIS in which the provider is accepting orders. The hours entered will carry over with each subsequent vaccine order. Update day(s) and delivery hours in IRIS as needed when submitting vaccine orders. Do not place orders if the clinic is going to be closed for an extended period of time.

VFC staff shall:

- Process vaccine orders in the order they are received.
- Review each vaccine order to verify need for quantity of vaccine ordered. The amount of vaccine ordered is compared to:
 - Recommended vaccine order quantity
 - Number of doses on hand
 - Vaccine expiration dates
 - Single antigens and combination vaccines in inventory
 - Doses administered for similar time period 12 months earlier
 - Doses distributed during last quarter
 - Provider profile

- Contact providers with orders requiring follow up to:
 - Review vaccine needs with the provider to verify and approve the vaccine order.
 - Instruct provider to adjust vaccine order if the need is not supported, and resubmit for processing.
 - Discuss vaccine needs when a recommended vaccine order quantity is suggested in IRIS but no doses are ordered by provider.
- Approve vaccine order in IRIS when review is completed and order is verified.
- Make changes to vaccine order if needed and process order in IRIS.
- Submit order to McKesson for distribution.

Ordering Varicella Containing Vaccine

Prior to ordering varicella-containing vaccine, providers must complete a Varicella-Containing Vaccine Storage Survey ([Appendix 4](#)) and receive approval by the VFC program coordinator to ensure varicella vaccine will be stored appropriately. The VFC Program uses this survey to assess the clinic's ability to store varicella-containing vaccine. All VFC varicella-containing vaccine orders will be shipped directly from the manufacturer (Merck). The maximum time required for vaccine orders to be processed and shipped is 30 days.

Receiving Vaccine Shipments

All clinic staff who may be involved in deliveries shall be trained to immediately notify vaccine coordinator or alternate (back-up) coordinator when deliveries arrive and ensure vaccines and diluents are properly stored immediately upon receipt.

Do NOT leave shipping container unpacked and unattended as vaccines and diluents inside might warm to inappropriate temperatures and become unusable. Staff members who accept deliveries for facility must be aware vaccine deliveries require immediate attention and know their responsibility in assuring the cold chain is maintained.

Appropriate clinic staff must be on site and available to receive vaccine at least one day a week other than Monday, and for at least four consecutive hours during that day.

Upon receipt of a vaccine shipment, providers must:

- Unpack vaccine shipment immediately.
- Check vaccine temperature monitors.
- Inspect the vaccine and packaging for damage.
- Compare ship date with date vaccine shipment arrived to determine time in transit.
- Cross check the vaccine received with the shipping invoice to match the number of doses, lot number and expiration dates. If there is a discrepancy with the vaccine order, or if vaccine was in transit more than three days, contact the VFC Program at 1-800-831-6293, ext. 5. Document on the invoice the date vaccine was received.
- Maintain vaccine shipping invoices for both public and private inventory for a minimum of three years.
- Store vaccine immediately at appropriate temperatures and according to manufacturers' product specifications.
- Take proper action if the cold or warm monitors are activated.

- VFC vaccine shipments received from McKesson contain cold and warm exposure indicators to assure the enclosed vaccines are received in manufacturer-recommended conditions. Instructions for reading the monitors are printed on the monitor cards.
- VFC direct shipments of frozen vaccine (varicella-containing) are shipped in specialized boxes and do not contain temperature indicators. Varivax, Zoster, ProQuad are shipped with frozen gel packs as refrigerant in the shipping container. No heat exposure indicator is included in the cooler; the gel packs and shipping containers are designed to maintain proper temperatures for four days from the shipment date on the packing list.
- Document warm or cold monitor readings if indicative of out-of-range temperature exposure, and contact the Iowa Immunization Program at 800-831-6293, ext. 5 for further guidance. Store the vaccine at appropriate temperatures. Mark the vaccine “Do Not Use” so the potentially compromised vaccines can be easily identified and not used until viability of vaccine is determined. Document action taken based on Immunization Program instructions.
- “Receive” VFC vaccine orders electronically into the organization’s IRIS inventory. Failure to receive vaccine orders in IRIS may result in inaccurate vaccine inventory, unaccounted for vaccines and errors in VFC vaccine doses administered reporting.

Vaccine Management

Vaccine Storage and Handling
Vaccine Storage and Handling Plan
Storage Unit Requirements
Temperature Monitoring
Vaccine Inventory Management
Vaccine Borrowing
Viable Vaccine Transfers
Accountability
Vaccine Restitution Policy
Administration Fees
Office Visit Fee

Each VFC provider must designate one staff member as the primary vaccine coordinator and at least one back-up coordinator who is able to perform the same responsibilities as the primary vaccine coordinator. These positions shall be responsible for oversight of vaccine management within the clinic and serve as the VFC contact for the office. Providers are required to notify the Iowa Immunization Program and update contact information in IRIS when there is a change in vaccine coordinators. To make changes for all organization contacts, IRIS Admin Users shall follow these steps:

- Open IRIS and select the Manage Access/Account link on the top menu panel.
- Select Edit Organization on the left menu panel.
- Enter the organization name in the search string, then select 'search'. The full name or part of the organization name can be entered when searching.
- Select the organization hyperlink in the Name column of the search results section.
- Scroll down to the Individual Contacts section. Review and update your organization's VFC contact information.
- Select the Edit icon if a contact needs to be changed or updated.
- Scroll down to the bottom of the page, and the contact's details will be displayed in the Edit Contact section. Make necessary changes, then select 'Apply'. Repeat as necessary for all contacts.
- Select the 'Save' button at the top of the Edit Organization page once necessary updates have been made. A red message will display at the top of the page to confirm changes were saved.

Proper management of vaccine is one of the most important activities conducted by a provider. The following sections describe the key elements and requirements of vaccine management for VFC providers.

Vaccine Storage and Handling

Vaccines must be maintained properly to protect viability. Adhering to proper storage and handling procedures will minimize the potential for vaccine loss and wastage. Providers should consult CDC's Vaccine Storage and Handling webpage available at

<http://www.cdc.gov/vaccines/recs/storage/default.htm> for the most current information regarding vaccine storage and handling. This should be the primary resource for vaccine storage and handling questions.

Vaccine Storage and Handling Plan

Storage and handling errors in which vaccines are compromised are costly. Vaccines must be stored properly from the time they are manufactured until they are administered. Exposure to temperatures outside recommended ranges will reduce potency and increase the risk recipients are not protected. When vaccine shipments are received, it is important to immediately store vaccine appropriately.

VFC Program providers must develop and maintain a written routine and emergency Vaccine Storage and Handling Plan and annually train ALL staff to safeguard vaccine supplies. The Immunization Program developed a Vaccine Storage and Handling Plan template ([Appendix 5](#)) to assist providers. The plan should be posted on or near the vaccine storage unit so it is easily accessible. At a minimum, the plan must be reviewed and updated annually, or any time there is a change in staff with responsibilities specified in the plan. A log with staff member's name and date of training should be kept as documentation.

Storage Unit Requirements

Refrigerators and freezers used for vaccine storage must:

- Maintain appropriate temperature range.
- Provide sufficient room to store water bottles in the refrigerator and frozen coolant packs in the freezer to stabilize the temperature.
- Be large enough to hold the year's largest inventory without crowding.
- Include a working certified and calibrated thermometer placed in a central area inside each storage compartment.
- Protect the power source with warnings such as "Do Not Disconnect" labels at the electrical outlet and the circuit breaker, back-up generators and/or developing appropriate policies/protocols.
- Be dedicated to vaccine storage.

Vaccine Storage Unit Recommendations

The following list provides guidance on types of storage units, in order of preference, offering greater assurance of proper temperatures based on equipment testing by the National Institute of Standards and Technology (NIST).

- Purpose built or pharmaceutical grade unit
 - Medical grade (pharmacy or blood bank) purpose built refrigerator units provide a stable, uniform controlled cabinet temperature with minimal temperature fluctuation.
- Separate stand-alone refrigerator or freezer units
 - A stand-alone refrigerator and freezer unit is a self-contained unit that only refrigerates or freezes and is suitable for vaccine storage.
 - Frost-free or automatic defrost cycle units are preferred.
- Refrigerator compartment only of a combination household refrigerator/freezer unit
 - Typical household single-condenser combination refrigerator/freezer units are less capable of simultaneously maintaining proper storage temperatures in refrigerator and freezer compartments.
 - Use only the refrigerator compartment for refrigerated vaccines.
 - Keep the freezer compartment on to maintain proper temperatures in the refrigerator. Place water bottles on top shelf, floor, and in door racks of refrigerator to maintain

stable temperatures and serve as a physical barrier to placing vaccines in an area where there is greater risk for temperature excursions.

- Use a stand-alone freezer for frozen vaccines.

Use of Dorm-Style Refrigerators

The use of dormitory or bar-style refrigerator/freezer units for storage of federally purchased vaccines is not allowed under any circumstances, including temporary storage. Performance testing indicates dorm-style units cannot reliably maintain appropriate vaccine storage temperatures. A dorm-style refrigerator is defined as a small combination refrigerator/freezer unit with one external door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. A dorm-style unit should never be used for storing vaccine, especially Varicella-containing vaccines.

Vaccine Storage Practices

The vaccine storage practices listed below are the responsibility of the provider/clinic vaccine coordinator or back-up coordinator.

- Maintain proper temperatures in the refrigerator, 35° through 46°F or 2° through 8°C.
- Store all varicella-containing vaccine (Varivax, Zoster, ProQuad) at -58° through +5°F or -50° through -15°C.
- Store MMR vaccine in either the refrigerator or freezer. Storing MMR vaccine in the freezer with MMRV may help prevent inadvertent storage of MMRV in the refrigerator. Diluent should NOT be stored in the freezer.
- Stabilize refrigerator and freezer temperatures with proper placement and use of water bottles and frozen packs.
- Store vaccines requiring refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent.
- Do not store vaccine in the door of the unit, crisper, or in the bottom of the unit.
- Remove vegetable bins from the refrigerator; replace with cold water bottles.
- Store vaccines requiring freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas.
- Store vaccine with enough space to allow cold air to circulate around the vaccine.
- Store all opened and unopened vaccines and diluents in their original packaging with lids closed to protect them for light until administration.
- Store vaccine products with similar packaging in different locations in the storage unit to avoid confusion and medication errors.
- Keep vaccines organized.
- Keep VFC vaccine separate from private vaccine and clearly label both.
- Open only one box of a particular vaccine at a time to control vaccine use and allow easier inventory control.
- Do not store food or drink in the storage unit.
- Limit access to the vaccine supply to authorized personnel only.

Stock Rotation

- Check and rotate stock regularly or when new vaccine inventory arrives.
- Ensure vaccine with the most current expiration dates are used first and are in front of vaccines with longer expiration dates.
- Train clinic staff regarding stock rotation.
- Train staff to distinguish VFC vaccine from private vaccine.

- Report VFC vaccine that will not be used and will expire within two to three months to the Iowa VFC Program at 1-800-831-6293.

Back-up Supplies/Facility

- It is important to have a back-up plan to appropriately store vaccine if vaccine storage equipment malfunctions or there is a power outage.
- Make formal arrangements (memorandum of understanding) with a back-up facility.
- Train a designated person and backup person at the facility to accept vaccine if it must be moved.
- Before moving vaccine, call the location to ensure the facility is available to store the vaccine (e.g., not damaged due to storms).
- If the back-up facility is not available contact the other facilities on the back-up facility list.

Temperature Monitoring

Temperature monitoring should be the primary responsibility of the provider/clinic vaccine coordinator and back up. VFC providers shall have protocols for training provider staff on proper assessment and interpretation of temperature data as well as proper documentation of findings. All staff monitoring temperatures must be trained on how to respond to and document actions taken when temperatures are outside the appropriate range. Temperature monitoring protocols include:

- Thermometers must be placed in central area of the storage unit directly with the vaccines.
- Designated staff must check and record refrigerator and freezer temperatures twice daily (at the beginning and end of each day).
- Each temperature reading must be accompanied by the time of the reading and the name or initials of the person who assessed and recorded the reading.
- Designated back-up staff should review the temperature log or stored temperature data at least weekly to ensure proper temperature recording and take action if out-of-range temperatures are found on the logs during review.
- Storage temperatures in both refrigerator and freezer units must be recorded on a temperature log. ([Appendix 8](#))
- The temperature log must be posted on the vaccine storage unit door or nearby in a readily accessible and visible location.
- Use of continuous temperature monitoring systems or digital min/max data loggers is recommended to monitor temperatures during non-business hours.
- If a continuous temperature monitoring and recording system is used, temperatures must be reviewed and recorded twice daily in an electronic format. If equipment does not record the time and date of staff's assessment of current temperature readings, the temperature readings must be printed twice daily from the system and the date and time applied to the printout. Daily data on temperatures must be provided in readable and interpretable printed form upon request.
- Temperature data, including hard copies, downloaded and electronic data, must be maintained for at least three years for each unit. This is useful to identify the duration of temperature variations.
- Immediate action must be taken if a temperature outside of the recommended range is found. Providers should immediately store vaccine appropriately and contact the VFC Program at 1-800-831-6293 ext. 2. Vaccine should be marked "do not use" and cannot be administered until the VFC Program has been contacted and decisions have been made regarding viability.

- Correct the problem as outlined in the [Vaccine Storage and Handling Plan – Section 8](#), Response to Improper Vaccine Storage and Handling. Each vaccine storage incident and action taken must be documented on the [Emergency Vaccine Response Worksheet](#).

Thermometer Requirements

Iowa VFC providers must have two thermometers in all refrigerator and freezer compartments used for VFC vaccine storage (two in the freezer, two in the refrigerator); a primary certified calibrated thermometer with valid and up-to-date certificate of calibration and a secondary thermometer.

Iowa VFC providers shall have at least one back-up thermometer with a current certificate of calibration on hand in case a thermometer in a storage unit unexpectedly stops working or needs to be replaced during calibration testing.

Thermometer Recommendations

CDC recommends use of a digital thermometer with a biosafe glycol-encased probe that measures liquid temperature. A glycol-encased probe more accurately reflects the temperature of the vaccine vial and does not register extraneous air temperature fluctuations. In addition to the use of a digital thermometer with a biosafe glycol-encased probe, the recommended temperature monitor should also provide continuous data monitoring information in an active display and be placed on the outside of the unit door to allow for reading temperatures without opening the unit door.

The data stored in the temperature monitor should be easily downloadable for review. This means the digital temperature monitoring device should have a detachable probe (kept in the glycol-filled bottle). A detachable probe facilitates downloading temperature data without removing the probe from the storage unit, and should simplify daily use and minimize operator caused temperature variability. The recommended digital data logger should also include the following capabilities:

- Alarm for out-of-range temperatures
- Current temperature, as well as minimum and maximum temperatures
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)
- Memory storage of at least 4,000 readings (device will not rewrite over old data and stops recording when memory is full)
- User programmable logging interval (or reading rate)

It is recommended minimum/maximum temperatures are checked and documented with each temperature reading. This helps to ensure temperature excursions will be identified more quickly and corrections made that can prevent vaccine loss, as well as minimize the inaccuracy of generalizing twice daily measurements.

CDC recommends the use of a digital data logger for clinics routinely closed for more than two consecutive days, and do not have staff that assess and record temperatures twice daily when the clinic is closed.

Vaccine Inventory Management

Public and private providers enrolled in the VFC program are responsible for the proper maintenance of their vaccine inventories. Key elements of VFC vaccine inventory management must include the following:

- At least one time each month and before ordering, vaccine and diluent doses must be counted. This will ensure enough vaccine doses to meet the needs of the facility, and is useful for checking accuracy of balance of doses in IRIS or stock record.
- VFC program providers tracking inventory in IRIS should print an inventory list from IRIS at least monthly to verify actual inventory in refrigerator/freezer. IRIS vaccine inventories should match actual refrigerator/freezer vaccine counts. If inventory discrepancies are identified, an inventory hand count should be conducted weekly.
- Rotate vaccine and check expiration dates.
- Expiration dates vary by type of vaccine or diluent and lot number. Expiration dates should be checked at least monthly and stock should be rotated to ensure the soonest to expire is in front. Expiration dates that list only month and year are viable through the last day of the month.
- Keep public (VFC) vaccine separate from private vaccine and clearly label both.
- Order vaccines in the appropriate amounts.
- Avoid stockpiling or inventory buildup.
- Maintain adequate inventories of VFC and private vaccine to eliminate occurrences of borrowing or transferring vaccine.

Vaccine Borrowing

All VFC-enrolled providers are expected to maintain adequate inventories of vaccine to administer to privately insured and VFC-eligible children. Vaccine borrowing must be due to an unforeseen delay or circumstance surrounding the vaccine ordered. Borrowing VFC vaccine to administer to non-VFC eligible patients, and vice versa, should only occur in extreme emergency situations.

Prior approval from the VFC Program is required for advance borrowing. Advance borrowing is intentional and known beforehand that VFC vaccine will be administered to private-pay patients or a private vaccine will be administered to VFC-eligible patients, due to insufficient clinic inventory. Accidental borrowing is when a dose of VFC vaccine is inadvertently administered to a private-pay patient, or when a private dose is inadvertently administered to a VFC-eligible patient.

Providers must document the following information on the Vaccine Borrowing Report Form ([Appendix 9](#)) once the borrowing and payback are completed and submit a copy to the Iowa VFC Program.

- Type of vaccine and number of doses borrowed
- Lot numbers of borrowed and replacement vaccine doses
- Reason for borrowing vaccine
- Date borrowed vaccine was replaced with vaccine

Borrowing VFC vaccine is the exception rather than the rule, and routine borrowing may be grounds for termination from the VFC Program. If a clinic continuously uses private stock or does not document usage appropriately, vaccine accountability procedures will be reviewed which may lead to further investigation and termination.

Viable Vaccine Transfers

A VFC provider may experience a situation where they have stock with a short timeline before expiration. Short-dated vaccine can be transferred to other VFC providers so it can be used prior to expiration. Providers must notify the VFC program coordinator of any vaccine doses that will expire before they can be administered.

Short-dated vaccine can be transferred to other VFC providers only under the following conditions:

- Prior approval of vaccine transfers between providers must be granted from the VFC Program by calling 1-800-831-6293. The following information is needed by the VFC Program to complete a vaccine transfer:
 - Vaccine type
 - Lot number
 - Expiration date
 - Number of doses
 - VFC PIN of transferring and receiving providers
- The cold chain must be maintained during the transfer.
- After receiving approval from the VFC Program, providers must:
 - Document vaccine transfer information on the VFC Vaccine Transferred Between VFC Providers form ([Appendix 10](#)) and fax form to VFC Program Coordinator with each vaccine transfer.
 - Document in IRIS all vaccine transferred to another provider. ([Appendix 11](#))

Accountability

Vaccine accountability is a cornerstone of the VFC Program. The VFC Program is a federally funded program with a national budget approaching \$4 billion. The VFC vaccine budget requires considerable attention regarding program accountability at the federal, state, and provider level. It is critical all doses of vaccine distributed to providers are accurately accounted for by performance of the following requirements:

- Administer VFC vaccine only to VFC-eligible children
 - VFC providers are responsible for ensuring and verifying all children are screened for eligibility at every immunization visit.
- Report all doses of VFC vaccine administered
 - All administered doses must be entered in IRIS by VFC providers who manage inventory in IRIS. VFC providers who do not manage inventory in IRIS must record and submit the Monthly Doses Administered Report form. ([Appendix 12](#))
- Report all vaccine loss to the VFC program
 - VFC providers using IRIS shall document vaccine loss using appropriate reasons provided in the registry. Expired vaccine is automatically adjusted by IRIS in the clinic inventory. For non-IRIS providers, wasted or outdated vaccine shall be reported on the Nonviable VFC Vaccine Return Form. When completing the report, include the reason vaccine is nonviable, number of doses, and vaccine lot number for each vaccine. Doses of vaccine reported in the vaccine loss column without an accompanying lot number cannot be accurately accounted for.
 - Nonviable VFC vaccine must be returned to McKesson Specialty Distribution. Return of nonviable vaccine to McKesson is necessary for the Immunization Program to receive

- federal excise tax credit. VFC providers shall document all nonviable expired or spoiled vaccine doses and submit report to the VFC Program on the Nonviable Vaccine Return Form. VFC providers shall return doses to McKesson Specialty Distribution within six months of expiration date for excise tax credit. The Nonviable Vaccine Return Form ([Appendix 13](#)) must be completed and faxed to the VFC Program when returning vaccine.
- VFC providers shall contact the Iowa VFC Program for instructions when vaccine is wasted because of a storage and handling incident. Vaccine deemed nonviable as a result of a storage and handling incident must be reported on the Nonviable Vaccine Return Form for each event.

Vaccine Restitution Policy

Effective November 1, 2011, the Iowa Immunization Program implemented the following vaccine restitution policy as mandated by the Centers for Disease Control and Prevention, Vaccines for Children Program requirements.

The purpose of this policy is to establish requirements for VFC Program providers to replace, at the provider expense, VFC vaccine unaccounted for and wasted (expired, spoiled or improperly stored) due to negligence on behalf of the provider. This policy is intended to address instances of extreme/on-going negligence resulting in the wastage of VFC vaccine.

Restitution Process

1. The Iowa VFC Program will review incidents of vaccine wastage to determine if restitution will be required. Restitution will be required for negligent provider activities or recurring issues that result in vaccine wastage.

Situations that may require provider restitution include, but are not limited to:

- Storage and handling errors resulting in vaccine wastage.
- Provider failing to act according to the agency/practice's Emergency Vaccine Storage and Handling Plan.
- Situations resulting in re-vaccination due to either improper vaccine administration or improper vaccine storage and handling resulting in the administration of non-viable vaccine. The provider may be responsible for purchasing private vaccine to re-vaccinate VFC eligible children.
- Excessive vaccine ordering leading to overstock resulting in vaccine wastage.
- Ordering combination vaccines which results in wastage of single antigen vaccines.

Situations that may not require restitution include, but are not limited to:

- A package not delivered to the provider in a timely manner or is otherwise damaged or exposed to improper temperatures during transit.
- A provider experiences a refrigerator/freezer malfunction, and the contracted alarm company does not notify the provider. The clinic should document the event and include a plan to prevent this from occurring in the future.
- Power is lost due to inclement weather or natural disaster.
- A vial is accidentally dropped or broken by a provider.
- Extraordinary situations, not listed above, deemed by the Iowa VFC Program to be beyond the provider's control.

2. When restitution is required, the provider will receive notification from the Iowa VFC Program detailing the number of vaccine doses requiring restitution. The invoice will detail the number of doses by vaccine manufacturer, type, and presentation (vials, syringes).
3. The provider will purchase vaccine equivalent to the notification received from the Iowa VFC Program. The vaccine shall be replaced within 30 days from the date of the notification unless mutually agreed upon by clinic staff and VFC program staff. The replenished vaccine shall be placed in VFC inventory and used to vaccinate VFC eligible children.
4. The privately-purchased vaccine shall consist of the same manufacturer, type, and presentation of vaccines identified for restitution by the Iowa VFC Program.
 - o Substitutions for vaccine manufacturer and presentation must be agreed upon by clinic staff and Iowa VFC Program prior to purchasing the vaccine.
5. A copy of the packing slip for the privately purchased vaccine shall be faxed to the Iowa VFC Program at 1-800-831-6292 attention VFC Program Coordinator.
6. Failure to comply with the restitution policy will result in suspension from the VFC Program. Suspended clinics will not be able to order VFC vaccine until vaccine has been replaced.
7. Failure to replace wasted VFC vaccine within 30 days of the clinic being placed on suspension will result in the clinic being terminated from the VFC Program. The provider may be permitted to re-enroll after the replacement of wasted VFC vaccine. Re-enrollment will be at the discretion of the Iowa VFC Program.
8. Providers who fail to comply with the Vaccine Restitution Policy will be referred to the Iowa Department of Human Services, Medicaid Program for further investigation of fraud and abuse.

Procedures to Minimize Vaccine Loss

Health care providers should implement and adhere to the following items to minimize vaccine loss:

- o Provide adequate vaccine storage and monitor storage conditions.
- o Do not over order or stockpile vaccine.
- o Do not assume vaccine is nonviable in the event of a storage problem. Contact the Iowa VFC Program immediately for instructions.
- o Count vaccine inventory at least monthly.
- o Check vaccine expiration dates at least monthly.
- o Rotate vaccine stock regularly; move earliest expiration dates to the front.
- o Report vaccine that will not be used and will expire within two to three months to the Iowa VFC Program.

Administration Fees

The federal VFC Program requires the Secretary, Department of Health and Human Services (HHS), to establish a limit on the dollar amount providers can charge and be reimbursed for administration of vaccine to VFC- eligible children.

Section 1928(c) (2) (c) (ii) of the Social Security Act (42 U.S.C. 1396s (c) (2) (c) (ii)) states: “The provider may impose a fee for the administration of a qualified pediatric vaccine so long as the fee in the case of a federally vaccine-eligible child does not exceed the costs of such administration (as determined by the Secretary based on actual regional costs for such administrations).”

The maximum administration fee established by HHS per injection for Iowa is \$19.68 ([Appendix 14](#)). The maximum administration fee is applicable to VFC-eligible patients who have no health insurance, are American Indian/Alaskan Native, and are underinsured (seen only at Rural Health Clinics, Federally

Qualified Health Centers and Local Public Health Agencies). The administration fees for these patients are charged to the patient, not the VFC Program or Medicaid Program. Providers may not deny immunization services for a patient's inability to pay the administration and office visit fees.

VFC Program legislation allows state Medicaid agencies discretion to pay an administration fee up to the regional maximum amount. The Iowa Medicaid Program has established maximum administration fees for Medicaid patients. The Medicaid fee schedule can be found at http://www.ime.state.ia.us/Reports_Publications/FeeScheduleAgreement.html.

If a child has primary insurance coverage and Medicaid as secondary they can receive VFC vaccine. Generally, providers are required to bill third party payers before Medicaid will make payment. However, in the case of preventive pediatric services (immunization), if the Medicaid agency is billed, it is required to make payment and then seek reimbursement from the third party (CMS refers to this as pay and chase). The Medicaid agency is to seek recovery as long as it is cost effective to do so. Questions regarding Medicaid billing should be directed to Provider Relations at 1-800-338-7909 or (515) 327-5120.

Office Visit Fee

The VFC Program allows providers to charge an office visit fee which is established by the facility. Discretion should be used to ensure that office visit fees do not create barriers for patients to receive immunizations. Participating in the VFC Program requires health care providers to not deny administration of a federally procured vaccine due to inability of the child's parent/guardian/individual of record to pay.

Fraud and Abuse

Definition of Fraud & Abuse

Examples of Fraud and Abuse

It is essential for providers participating in the VFC Program to fully understand program requirements and what constitutes fraud and abuse. The VFC Program routinely provides education to enrolled providers regarding VFC Program requirements. Consistent with fraud and abuse as defined in Medicaid regulations at 42 CFR § 455.2, and for purposes of this VFC Operations Guide, the following definitions will be used:

Definition of Fraud & Abuse

Fraud

Fraud is defined as an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Abuse

Abuse is defined as provider practices inconsistent with sound fiscal, business or medical practices, and result in an unnecessary cost to the Medicaid Program [and/or including actions resulting in an unnecessary cost to the Immunization Program, a health insurance company or a patient]; or in reimbursement for services not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices resulting in unnecessary cost to the Medicaid Program.

Examples of Fraud and Abuse

Fraud or abuse can occur in different ways. Some examples of fraud and abuse are:

- Providing VFC vaccine to non-VFC eligible children
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for VFC vaccine
- Charging more than the established maximum charge (\$19.68) for administration of a VFC vaccine to a federally vaccine-eligible child
- Denying VFC-eligible children VFC vaccine due to parents' inability to pay the administration fee
- Failing to implement provider enrollment requirements of the VFC Program
- Failing to screen for and document eligibility status at every visit
- Failing to maintain VFC records and comply with other requirements of the VFC Program
- Failing to fully account for VFC vaccine
- Failing to properly store and handle VFC vaccine
- Ordering VFC vaccine in quantities or patterns not consistent with provider profiles or otherwise over ordering VFC doses
- Wasting VFC vaccine

The VFC Program provides education during the provider enrollment process and during VFC compliance site visits to help prevent situations that may constitute fraud and abuse. Lack of adherence to VFC Program requirements may lead to fraud and abuse. The VFC Program will investigate all allegations of fraud and abuse and determine appropriate action. If deemed necessary, the VFC Program will notify proper investigative agencies to conduct a full investigation.

Quality Assurance

Quality Assurance Review Assessment, Feedback, Incentives, and eXchange (AFIX)

Quality Assurance Review

Quality assurance involves review and evaluation of VFC provider practices and is a requirement of the VFC Program. Quality assurance is implemented through VFC provider site visits conducted by VFC Program representatives. The compliance site visits involve assessment of verbal, written, and visual evidence encountered during the visit to determine if provider sites are following VFC Program requirements and to assist with improving the overall VFC Program at the state level.

Quality assurance takes place during four types of site visits:

- Initial site visit
- Bi-annual compliance site visit
- Drop in storage and handling visit
- Assessment, Feedback, Incentives, and eXchange (AFIX) visit

Initial Site Visit

VFC staff will conduct an initial VFC enrollment site visit with all new providers enrolling in the VFC Program. The new enrollment visit ensures provider and office staff are educated on VFC Program requirements, have appropriate resources to implement the VFC Program requirements, that necessary paperwork is completed, and vaccine storage units can maintain appropriate temperatures. Vaccine will not be shipped until the initial site visit is complete.

Compliance Site Visit

VFC provider site visits help determine if VFC vaccines are being distributed, handled, and administered in accordance with laws and policies that govern the VFC Program.

Federal guidelines require the VFC Program to conduct compliance site visits at each VFC enrolled facility. The purpose of the site visit is to:

- Review VFC eligibility screening procedures.
- Verify information in the provider profile.
- Administer the VFC provider site visit questionnaire.
- Review VFC vaccine administration, storage and handling.
- Ensure VFC Program policies are being properly implemented.
- Provide feedback and, as necessary, request corrective action and follow up of identified problems.

Drop In Storage and Handling Visits

These unannounced visits serve as a “spot check” for proper storage and handling practices. Providers are prioritized and selected based on the provider’s previous history with storage and handling compliance issues. The goal of the visits is to provide guidance and education on proper storage and handling to ensure all VFC-eligible children are receiving properly managed vaccines.

Assessment, Feedback, Incentives and eXchange (AFIX)

AFIX is one of the most effective strategies for improving immunization coverage levels and standards of practice at the provider level. AFIX stands for:

- Assessment of immunization levels
- Feedback of immunization information to key staff
- Incentives for performance
- eXchange of information on best practices to improve immunization coverage levels

The goal of AFIX is to ensure vaccines reach all children served in accordance with the ACIP schedule. The AFIX process is a partnership between VFC Program staff and the provider to improve immunization coverage levels.

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